

REMARKS

Claims 1-7 and 11 are pending in the application.

By this amendment, Applicants amend claims 1 and 7. Applicants submit that these amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. In addition, entry of these amendments is requested because they are necessary to define and clarify the invention in light of the cited prior art. Therefore, this Amendment should allow for immediate action by the Examiner.

In the Office Action of August 1, 2003, the Examiner rejected claims 1-5, 7, and 11 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,939,974 (Valentini). Applicants respectfully traverse this rejection.

In the last response, Applicants provided a declaration from Dr. Hyun Kim, an inventor on both the pending application and the Valentini patent. Applicants point out that Dr. Kim has intimate knowledge of both the Valentini patent and the pending application and as a result, his statements of fact should receive careful consideration. Dr. Kim's declaration described the insufficiencies of Valentini as a prior art document. Specifically, Dr. Kim described the compositions of Valentini as uninjectable and not pharmaceutically acceptable. The Examiner seems to disagree with Dr. Kim's assertions, yet has not provided any evidence to substantiate his position.

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It is well established that an Examiner must provide support for rejections based on facts within their own personal knowledge:

When a rejection is based on facts within the personal knowledge of the Examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the Examiner. *Manual of Patent Examining Procedure*, Section 2144.03.

In this Office Action, the Examiner makes several statements requiring support. For example, on page 2, the Examiner states that "liquids do not have porosity, solids do." Applicants do not agree with this statement. On page 8 of the specification, Applicants describe the use of scanning electron microscopy to determine the porosity of the liquid compositions of the invention. It is quite clear from the specification and Dr. Kim's declaration that the compositions of the invention are not solids, yet they possess varying degrees of porosity. As stated in Dr. Kim's declaration, the liquid intermediate composition of Valentini has a level of porosity prohibitive to injection. In light of this contradictory evidence, Applicants therefore request that the Examiner support his assertion that liquids cannot have porosity with evidence or an affidavit.

On page 3, the Examiner contends that any paste that can be delivered through a caulking gun may be "injectable." Applicants disagree with this statement as well. However, Applicants have amended claims 1 and 7 to require that the composition be deliverable to a patient by injection. It is well accepted that an injection of a patient requires the entry of a needle or other delivery device through the skin into the patient without opening a wound. This could not be achieved with a caulking gun or its equivalents. In light of this amendment, Applicants request that this claim be withdrawn.

The Examiner attempts to support his contention that the compositions of Valentini are pharmaceutically acceptable by arguing that the final composition of Valentini is pharmaceutically acceptable. The Examiner, however, is not using the solid final composition of Valentini to support his rejection of the pending claims. It is clear from Valentini's disclosure that the final, pharmaceutically acceptable composition is not injectable. Therefore, the Examiner relies on the liquid intermediate composition of Valentini to support his rejections. The intermediate composition, however, is not pharmaceutically acceptable because it contains pore formers and is solubilized in toxic organic solvents. The compositions of Valentini only become pharmaceutically acceptable when the pore formers and solvents are removed. The removal of the solvents inherently causes the composition to solidify, rendering it uninjectable. Therefore, at no point does Valentini teach or even suggest an injectable, pharmaceutically acceptable composition.

In light of the Examiner's lack of supporting evidence and the insufficiency of Valentini as a reference, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for claims 1-5, 7, and 11. Applicants therefore request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

The Examiner also rejected claim 6 as allegedly obvious over Valentini in view of U.S. Patent No. 6,187,742 (Wozney). The Examiner contends that "the fact that Wozney et al. place only limited emphasis on the carrier provides sufficient motivation to substitute one BMP for another in the instant carriers." As demonstrated in the last response, and reiterated here, Valentini is insufficient to establish obviousness, and the

teachings of Wozney do not cure this deficiency. The Examiner acknowledges that Wozney et al. does not remedy a deficiency in the carrier of Valentini. The carrier is the critical deficiency in Valentini, as discussed in detail above. Therefore, all of the arguments set forth above regarding Valentini apply equally to the rejection of claim 6 over the combination of Valentini and Wozney. Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness for claim 6 and request that this rejection be withdrawn.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing pending claims 1-7 and 11-13 in condition for allowance.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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